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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,224	BENSON ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-76 and 79-107* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-76 and 79-107* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claims 54-76 and 79-107 are pending in the application.

[2] Applicant's amendment to the claims, filed September 17, 2004, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

[3] Applicants' arguments filed on September 17, 2004 have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[4] The text of those sections of Title 35, U.S. Code not included in the instant action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[5] Claim(s) 83, 86-87, 90, 93-100, 103, and 105-107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

[a] Claims 83, 86-87, 90, and 93-100 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. Claims 93-100 are

drawn to methods for preparing crystals of beta secretase in the presence of an inhibitor. However, there is no indication that the crystals of beta secretase produced by the claimed methods, *i.e.,* the crystals of claims 83, 86-97, and 90, have the essential element of the inhibitor present in the crystal. As such, the crystals and methods are incomplete.

[b] Claims 103 and 105 (claims 106-107 dependent therefrom) are indefinite in the recitation of "a buffer" as it is unclear as to the composition of the recited buffer. It is suggested that applicants clarify the meaning of the claims.

Claim Rejections - 35 USC § 112, First Paragraph

[6] Claim(s) 86, 90, 95-96, 99-100, 103, and 105-107 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 86 (claims 95-96 dependent therefrom) and 90 (claims 99-100 dependent therefrom) recite the limitation "a = b = about 112 Å, c= about 110 Å." Claims 103 and 105 recite the limitation "a buffer present in about 10 mM to about 200 mM concentration." Claim 105 (claims 106-107 dependent therefrom) recites the limitations "human beta secretase at a concentration of about 18 mg/ml to about 40 mg/ml," "17% by weight to about 22% by weight of a glycol," and "a pH of about 4.0 to about 4.7." The examiner can find no support for the recited limitations in the specification, particularly

where applicants direct the examiner's attention for such support (p. 11 of the response filed September 17, 2004). The examiner invites applicants to show support for these recited limitations.

[7] The written description rejection of claims 54-76, 79-82, 84, 88, 91-93, 95, 97, 99, and 101-107 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in item [12] of the Office action mailed March 17, 2004 and for the reasons stated below.

[8] RESPONSE TO ARGUMENTS: Applicants argue "suitable" species of beta-secretase and inhibitors are described in the specification and additional species of such are known in the art and could be used in methods and crystals of the claimed invention, allegedly evidenced by: 1) the examiner has acknowledged other species of beta-secretase are known in the art and the specification provides methods for determining homology of other species of beta-secreatase; 2) the examiner has acknowledged other species of beta-secretase inhibitors are known in the art; 3) due to routine variation, applicants are entitled to a reasonable range of unit cell dimensions to protect their disclosed invention; and 4) it would be obvious to one of skill in the art that for trigonal space groups, a=b and that no correction is required. Applicants' argument is not found persuasive.

The examiner maintains the position that the single representative species of the genus of human beta secretases crystallized in the presence of a genus of inhibitors by the method of claims 54-71, 93, 95, 97, 99, and 101-107 i.e., the human beta secretase of SEQ ID NO:1 crystallized in the presence of the inhibitor of Figure 1, and the genus

of beta secretase crystals of claims 72-76, 79-82, 84, 88, and 91-92 as disclosed in the specification, i.e., a crystal of the purified human beta secretase of SEQ ID NO:1 complexed with the inhibitor of Figure 1 having a trigonal space group symmetry of $P3_221$ and the unit cell dimensions of a=b=112±20 Å, c=110±20 Å, and $\alpha=\beta=90^{\circ}$ and $\gamma=120^{\circ}$ or a=b=99±35 Å, c=117±35 Å, and $\alpha=\beta=90^{\circ}$ and $\gamma=120^{\circ}$, fails to represent the entire genus.

In response to applicants' argument that the examiner has acknowledged that other species of beta-secretase are known in the art and the specification provides methods for determining homology of other species of beta-secreatase, it is noted that the crystals/methods of claims 54-74, 79-82, 88, 91-92, and 101-107 are not so limited to those beta-secretases of SEQ ID NO:1 and the prior art. Further it is noted that, while the examiner has clearly acknowledged the presence of beta-secretases that are structurally distinct from SEQ ID NO:1 (p. 5, top, of the Office action mailed March 17, 2004), there is no description in the prior art or the specification of the structures of the *crystals* that would result from crystallization of these beta secretases and, in view of the cited prior art (pp. 11-12 of the Office action mailed August 12, 2003 and and pp. 8-9 of the Office action mailed March 17, 2004), there is no way to predict *a priori* the structure of a protein crystal based solely on its amino acid sequence. As such, the prior art does not describe *crystals* of these additional species of human beta secretase. In this case, the claims encompass a widely variant genus of crystallized and/or purified beta-secretase enzymes, including all mutants and variants of a human beta secretase or a beta secretase from any source and mutants and variants thereof. It should be

noted that, while some claims are limited to a "human beta secretase," there is no description in the specification of those those characteristics of a "human beta secretase" that distinguish a "human beta secretase" from the larger genus of beta-secretase proteins.

In response to applicants' argument that the examiner has acknowledged that other species of beta-secretase inhibitors are known in the art, it is noted that the crystals/methods of claims 54-76, 79, 81, 84, 88, 93, 95, 97, and 99 are not so limited to those beta-secretase inhibitors of Figure 1 and the prior art. Further it is noted that, while the examiner has clearly acknowledged the presence of beta-secretase inhibitors other than the inhibitor of Figure 1 (pp. 11-12 of the Office action mailed August 12, 2003), there is no description in the prior art or the specification of the structures of the *crystals* that would result from crystallization of these beta secretase inhibitors with a given beta secretase and, in view of the cited prior art (pp. 11-12 of the Office action mailed August 12, 2003 and pp. 8-9 of the Office action mailed March 17, 2004), there is no way to predict *a priori* the structure of a protein crystal in complex with a given inhibitor. For example, the structure of a crystal resulting from a protein complexed with an inhibitor is dependent upon the method by which the complex was formed, *e.g.*, by co-crystallization of the inhibitor/protein or by soaking the inhibitor with a crystallized protein. As such, the prior art does not describe *crystals* of these additional species of beta secretase inhibitors in complex with a beta secretase. In this case, the claims encompass a widely variant genus of crystallized and/or purified beta-secretase enzymes in complex with a cognate inhibitor, including any inhibitor or beta secretase.

In response to applicants' argument that due to routine variation, applicants are entitled to a reasonable range of unit cell dimensions to protect their disclosed invention, it is noted that the examiner has indicated such variation in unit cell dimension as an embodiment that has been fully described, *i.e.*, a crystal of the purified human beta secretase of SEQ ID NO:1 complexed with the inhibitor of Figure 1 having a trigonal space group symmetry of $P3_221$ and the unit cell dimensions of a=b=112±20 Å, c=110±20 Å, and $\alpha=\beta=90^\circ$ and $\gamma=120^\circ$ or a=b=99±35 Å, c=117±35 Å, and $\alpha=\beta=90^\circ$ and $\gamma=120^\circ$.

In response to applicants' argument that it would be obvious to one of skill in the art that for trigonal space groups, a=b and that no correction is required, it is noted that claim 73 is not so limited to a trigonal space group. Further, regarding claim 74, if one of skill would know that the unit cell dimension of a is necessarily equal to b in a crystal having the trigonal space group symmetry $P3_221$, it is not clear to the examiner as to why applicants have not amended the claim so as to clarify the meaning of the claim. In the absence of such amendment, it would appear that applicants are attempting to claim a crystal having the trigonal space group symmetry $P3_221$ wherein a is not equal to b. However, there is no description of such a crystal in the specification to represent such a species of crystal. As such, the specification fails to describe all members of the claimed genus of beta secretase crystals.

Regarding claims 101-107, the specification fails to describe even a single representative species of methods for crystallizing human beta secretase in the presence of a substrate. Given the lack of description of a representative number of

species, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention. For detailed reasoning as to why a representative number of species is required to describe a recited genus, applicants' attention is directed to item [21] of the Office action mailed August 12, 2003.

[9] The scope of enablement rejection of claims 54-76, 79-84, and 86-107 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in item [13] of the Office action mailed March 17, 2004 and for the reasons stated below.

[10] RESPONSE TO ARGUMENT: Applicants argue that the references of Chopra et al., Tang et al., and Hong et al. (cited in a previous Office action) disclose methods for crystallizing human beta secretase at a pH different from the pH of the crystallization buffer as recited in claims 54-71. Applicants argue claims 72-76 are directed to crystals and not methods of crystallization. Applicants state that they do not understand the examiner's intent in citing these references and invite the examiner to clarify the statements. Applicants' argument is not found persuasive.

The examiner maintains the position that the specification is enabling only for a method for crystallizing the human beta secretase of SEQ ID NO:1 complexed with the human beta secretase inhibitor of Figure 1 by preparing purified human beta secretase of SEQ ID NO:1 in the presence of the inhibitor of Figure 1 to a final concentration of 18-40 mg/mL beta secretase protein and 2 mM inhibitor and crystallizing human beta secretase using the hanging drop method in a solution of 17-20% PEG 3000, 0.1 M sodium acetate, pH 4.5 at 20 degrees Celsius and optionally wherein the solution

contains 10% glycerol or 10% ethylene glycol and a crystal of the human beta secretase of SEQ ID NO:1 complexed with the inhibitor of Figure 1 having a trigonal space group symmetry of $P3_221$ and the unit cell dimensions of a=b=112±20, c=110±20, and $\alpha=\beta=90^\circ$ and $\gamma=120^\circ$ or a=b=99±35, c=117±35, and $\alpha=\beta=90^\circ$ and $\gamma=120^\circ$. In response to applicants confusion regarding the citation of the references of Chopra et al., Tang et al., and Hong et al., as stated in a previous Office action, these references have been cited as exemplifying the teachings of Branden et al. and Drenth, teaching that protein crystallography is highly unpredictable and is critically dependent upon the crystallization conditions as even small changes in the crystallization parameters can cause the molecules to pack resulting in different crystal forms. For example, Chopra et al. teach crystallization of human beta secretase complexed with a peptide inhibitor in a buffer at pH 6.5 with a resulting crystal having an orthorhombic space group symmetry of I222 (paragraph 0047) while Tang et al. teach crystallization of human beta secretase complexed with the inhibitor OM99-2 in a buffer at pH 6.4 with a resulting crystal having an orthorhombic space group symmetry of $P2_12_12_1$ (column 31, top). In this way, the references show that even minor alterations to the crystallization buffer, *i.e.*, pH 6.4 of Tang and pH 6.5 of Chopra, can result in crystals having different space group symmetries. Applicants acknowledge this unpredictability (p. 16, bottom of the response filed September 17, 2004) by stating, "the type of beta secretase crystal grown may depend on the pH used in the crystallization method." Furthermore, as stated in a previous Office action and undisputed by applicants, even in a pH range recited in claims 54-71 and 93-100, the structure of the crystal is highly unpredictable as

evidenced by Beyer et al. who teach crystallization of human beta secretase in a buffer having pH 4.0 in the presence (Example 6) and absence (Example 9) of an inhibitor resulted in crystals having a space group ($P2_12_12_1$) and unit cell dimensions that are distinct from the crystals as disclosed in the instant specification. In this case, the working examples provided in the specification fail to enable the entire scope of claimed methods/crystals.

Applicants argue replacement of methionine by selenomethionine is well known in the art of protein crystallography and the technique is useful because the incorporation of the heavy atoms does not substantially disrupt the crystal structure as exemplified by Hendrickson et al. Applicants argue that a skilled artisan would have a reasonable expectation that of crystallizing a protein having selenomethionine incorporated therein without disrupting the crystal structure. Applicants' argument is not found persuasive.

It should be noted that the examiner's arguments are deemed to be sufficient to rebut applicants' arguments. However, in the interest of clarifying the examiner's argument, it is noted that there is no way *a priori* to predict whether selenomethionine replacement of methionine would or would not disrupt the structure of a crystal. Applicants' exemplary reference of Hendrickson et al. fails to establish that selenomethionine replacement in the protein of SEQ ID NO:1 or any other beta secretase would not disrupt crystal structure. Applicants are invited to provide such evidence. In the absence of such evidence, it remains highly unpredictable as to

whether such replacement would affect the resulting crystal structure, particularly in view of the references of Branden et al. and Drenth et al.

Applicants argue the examiner has failed to rebut their argument addressing using the disclosed crystals in cross-seeding. Again, applicants' arguments are not found persuasive.

It should be noted that the examiner's arguments are deemed to be sufficient to rebut applicants' arguments. However, in the interest of clarifying the examiner's argument, it is noted that the methods/crystals of the claims are not so limited to being crystallized using a cross-seeding technique. Even assuming *arguendo* the claimed methods/crystals were limited to being crystallized by a cross-seeding technique, the full scope of the claims would not be enabled at least in view of the high level of unpredictability in crystallizing a protein as evidenced by Branden et al. and Drenth et al. (cited by applicants).

Double Patenting Rejection(s)

[11] The provisional double patenting rejection of claims 54-71 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-18 of copending Application No. 10/027,277 and the provisional double patenting rejection of claims 54, 56, and 72-76 under 35 U.S.C. 101 as claiming the same invention as that of claims 4, 5, and 24-28 of copending Application No. 10/144,441 are maintained for the reasons of record as set forth in items [15] and [16] of the Office action mailed March 17, 2004. It should be noted that claims 19-23 of the '277 application have been withdrawn from consideration

by the examiner and thus are no longer included in the instant rejection. Applicants do not dispute the examiner's position. Applicants argue that because the rejections are provisional, a response to the rejections is deferred until allowable subject matter is indicated. Applicants' argument is acknowledged and the rejection is maintained.

[12] The provisional double patenting rejection of claims 54, 55, and 57-71 as being unpatentable over claims 1-3 and 6-23 of copending Application No. 10/144,441, the provisional double patenting rejection of claims 54-69 as being unpatentable over claims 7-23 of copending Application No. 10/143,502, and the provisional double patenting rejection of claims 54-67 as being unpatentable over claims 12-26 of copending Application No. 10/143,723 under the judicially created doctrine of obviousness-type double patenting are maintained for the reasons of record as set forth at items [18]-[20] of the Office action mailed March 17, 2004. Applicants do not dispute the examiner's position. Applicants argue that because the rejections are provisional, a response to the rejections is deferred until allowable subject matter is indicated. Applicants' argument is acknowledged and the rejection is maintained.

[13] Claims 93-100 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/027,277. This rejection is necessitated by amendment. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46

USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 93-100 of the instant application and claim 1 of the '277 application are directed to methods for crystallizing a human beta secretase in the presence of an inhibitor. The claims differ in that the claims of the instant application are limited to crystallizing SEQ ID NO:1 or a selenomethionine variant thereof and optionally wherein the inhibitor is the inhibitor of Figure 1. The specification of the '277 application supports an embodiment of a method of crystallizing SEQ ID NO:1 or a selenomethionine variant thereof in the presence of the inhibitor of Figure 1 in a buffer having a pH of about 3.5 to about 5.5 (see, *e.g.*, pp. 3, 5, 18, 22, and 38-39 of the specification of the '277 application). Claims 93-100 cannot be considered to be patentably distinct over claim 1 of the '277 application when there is a specifically disclosed embodiment in the '277 application that falls within the scope of claims 93-100 because it would have been obvious to one of ordinary skill in the art to modify the method of claim 1 of the '277 application by selecting a specifically disclosed embodiment that supports these claims. One of ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within the claims.

[14] Claims 79-90 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27-28 of copending Application No. 10/144,441. This rejection is necessitated by amendment. An obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 79-90 of the instant application and claims 27-28 of the '441 application are directed to crystals of beta secretase. The claims differ in that the claims of the instant application are further limiting in the recited unit cell dimensions and (in part) further comprise an inhibitor and optionally wherein the inhibitor is the inhibitor of Figure 1. The specification of the '441 application supports an embodiment of the crystals of claims 79-90, (see, *e.g.*, pp. 3, 5-6, 20-22, and 36-38 of the specification of the '441 application). Claims 79-90 cannot be considered to be patentably distinct over claims 27-28 of the '441 application when there is a specifically disclosed embodiment in the '441 application that falls within the scope of claims 79-90 because it would have been obvious to one of ordinary skill in the art to modify the crystal of claims 27-28 of the '441 application by selecting a specifically disclosed embodiment in the specification of the '441 application that supports these claims. One of ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within the claims.

Conclusion

[15] Status of the claims:

- Claims 54-76 and 79-107 are pending.
- Claims 54-76 and 79-107 are rejected.
- No claim is in condition for allowance.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Thursday and on alternate Fridays from 7:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman

David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1652
10-14-04